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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,612	09/13/2004	David Marston Band	BAND3004/REF	4899

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EXAMINER

BERTRAM, ERIC D

ART UNIT PAPER NUMBER

3766

DATE MAILED: 08/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/506,612	Applicant(s) BAND ET AL.	
	Examiner Eric D. Bertram	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17, 19-23 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17, 19-23 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/13/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 9/13/04 was filed in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3, 12-14, 16, 17, 20-22 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Tockman et al. (US 5,540,727, hereinafter Tockman). Tockman discloses a system and method for synchronizing respiratory changes with changes in the cardiac output and the arterial pressure of a patient. Tockman describes implanting cardiac pacing wires to stimulate the right atrium with electrode 22, the left ventricle with electrode 27 and the right ventricle with electrode 26 (Col. 3, lines 20-27). The cardiac output and arterial pressure of the patient is continuously monitored and recorded through sensors 46 and 48 (Col. 4, lines 5-12). Furthermore, sensors 26 and 28 are

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used to continuously monitor and record an impedance signal representative of the inspiratory and expiratory activity of the patient. Finally, Tockman describes that a synchronization of changes in cardiac output and arterial pressure with respiratory changes is obtained while the impulses sent to the cardiac electrodes is varied (Col. 6, lines 7-12 and figure 2).

5. Regarding claim 3, the arterial pressure is measured with a pressure cuff, which is inherently a pressure transducer, and is connected to the system by what the Examiner considers to be an arterial line (Col. 4, line 10 and figure 1).

6. Regarding claims 12, 14, 20 and 22, Tockman discloses that the conduction delays are adjusted and varied using predetermined pacing modes, which the Examiner considers to be a predetermined matrix (Col. 3, lines 48-54).

7. Regarding claims 13 and 21, Tockman discloses the use of an external monitor/programmer 42 which displays and records cardiac parameters (Col. 3, line 55-Col. 4, line 13).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tockman in view of Band et al. (6,071,244, hereinafter Band '244). Tockman, as described above, discloses the applicant's basic invention including monitoring and recording the arterial pressure of the patient. Tockamn does not disclose, however, using the arterial pressure to calculate a nominal stroke volume of the patient. Attention is directed to the secondary reference of Band '244, which discloses methods for determining the nominal stroke volume of a patient from a measured arterial pressure using non-linear transformation, autocorrelation, and a look up table (Col. 2, line 27- Col. 3, line 20). Therefore, it would have been obvious to one of ordinary skill in the art to modify the method of Tockman in order to calculate the nominal stroke volume of a patient by using the established method of Band '244.

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12. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tockman in view of Band et al. (WO99/02086, hereinafter Band '086). Tockman, as described above, discloses the applicant's basic invention including monitoring and recording the arterial pressure of the patient. Tockamn does not disclose, however, using the arterial pressure to calculate a nominal stroke volume of the patient. Attention is directed to the secondary reference of Band '086, which discloses methods for determining the nominal stroke volume of a patient from a measured arterial pressure using Fourier analysis to obtain a modulus of the first harmonic, a non-linear transformation and a look up table (pages 4, 5 and 7). Therefore, it would have been obvious to one of ordinary skill in the art to modify the method of Tockman in order to calculate the nominal stroke volume of a patient by using the established method of Band '086.

13. Claims 11 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tockman in view of Official Notice and Reinhard (US 3,584,618). Tockman, as described above, discloses the applicant's basic invention, including detecting the respiratory cycle of a patient. However, Tockman does not utilize a strain gauge placed around the patient's chest to record the respiratory cycle. The Examiner takes Official Notice that the use of a strain gauge placed around the chest of a patient to monitor the respiratory cycle is notoriously old and well known in the art, with the cited Reinhard patent as but one example (see Col. 1, lines 24-25), and, as such, its use would have been obvious to one of ordinary skill in the art at the time of the applicant's invention.

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14. Claims 15 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tockman in view of Official Notice. Tockman, as described above, discloses the applicant's basic invention including providing pacing to the heart in order to maintain a predetermined pacing rate, but does not specifically disclose that the pacing rates should be kept between 80 and 100 beats per minute (bpm). However, this range is well known by those skilled in the art as the standard, safe heart rate range for the average healthy patient. Therefore, the Examiner takes Official Notice that maintaining a pacing rate between 80 and 100 bpm would have been obvious to one of ordinary skill in the art at the time of the applicant's invention.

Allowable Subject Matter

15. Claim 24 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Renirie et al. (US 6,141,590) discloses a method for respiration modulated pacing.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric D. Bertram whose telephone number is 571-272-3446. The examiner can normally be reached on Monday-Thursday and every other Friday from 9-6:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric D. Bertram
Examiner
Art Unit 3766


Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766

EDB